REMARKS

The applicant respectfully requests reconsideration of Claims 16-25 as amended, and consideration of new Claims 26-31. Claim 22 is amended for consistency with the specification, particularly at page 7, line 26.

Claims 16-25 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the present invention. In view of the amendment to Claim 16, it is believed that Claims 16-25 now meet the requirements of §112, second paragraph.

Claims 16-18 and 22-25 stand rejected under U.S.C. §102(b) as being anticipated by U.S. Patent 4, 958,634 (Jang). Jang discloses an angioplasty catheter in which one or more distal balloons are formed from a single monolithic piece of polymer material. In particular, a lumen is formed in the catheter to correspond to each desired balloon. The distal end of each lumen is sealed, and the balloon formed by applying pressure to the proximal end of the lumen and heating the outer wall while the catheter is inside a die. The outer wall is expanded against the die to determine the shape and dimensions of the balloon.

Without any apparent preference, Jang lists the following possible approaches for forming the bond necessary to seal each lumen distal end: heat bonding, vulcanization bonding, solvent bonding, ultrasonic welding, laser welding, and glue bonding. The balloon joints are semi-circular around the catheter shaft. See Jang at column 11, lines 43-62.

There is no discussion of any of these bonding approaches. In particular, there is no mention of the advantages of laser bonding as compared to the other methods, nor is there any indication as to what method of laser welding is recommended. Jang does not even mention crystallization. Thus, there is no

apparent recognition that catheter crystallization leads to undesirable stiffness. Jang fails to perceive the problem, and therefore proposes no solution.

In connection with this rejection, it is asserted in the office action that Jang teaches the claimed catheter and teaches laser bonding. This assertion is made primarily with reference to column 14, lines 47-51 of Jang.

This assertion is respectfully traversed. The cited material, like the previously referenced material from column 11 of Jang, is no more than a list of several approaches to fusion bonding that fails to distinguish laser bonding from any of the other forms. Specifically, the list in column 14 includes heat bonding, RF bonding, laser bonding, solvent welding, adhesive bonding, and heat-shrink bonding.

Claim 16 requires a fusion bond between catheter tubing and the neck regions of a polymeric dilatation balloon. Each fusion bond is within .030 inches of its associated tapered region. Each tapered region is substantially free of crystallization.

Assuming arguendo that the dies in Jang are shaped to provide the claimed tapered regions, and assuming further that the sealing bonds in Jang are immediately adjacent the tapered regions, there remains a total absence of any teaching that the tapered regions are free of crystallization.

In apparent recognition of this fact, it is asserted in the office action that the tapered regions of the Jang catheter would "inherently" be substantially free of crystallization. This assertion is respectfully traversed.

A fusion bond involves application of heat to the balloon and catheter materials, sufficient to cause the materials to fuse. The inevitable result is crystallization. Crystallization is not avoided, even when fusion is accomplished by laser

bonding. Rather, in accordance with the present invention the area of applied heat is precisely controlled through proper focusing of the laser, and axial conduction of the heat along the catheter and dilatation balloon is minimized by matching the laser wave length to the absorption characteristics of the polymer or polymers involved.

In the present specification, beginning at page 13, line 2, it is explained that polymeric materials do not absorb energy uniformly, but rather exhibit bands of markedly increased absorptivity. For example, polyesters exhibit a band of high energy absorption for wavelengths ranging from about 7-11 microns. This encompasses the 10.6 micron wavelength of the CO_2 laser. The polyethylene terephthalate balloon material also has high absorptivity of the 10.6 micron energy. Accordingly, there is virtually no substantial conduction of heat in either axial direction away from the bond site (page 13, lines 31-35).

Further, the laser source is preferably operated in the tem_{00} mode. The result is a focal area having a Gaussian energy distribution, with maximum energy at the center of the focal area (specification at page 12, lines 23-26).

The tendency of the matched polymeric material to absorb the laser energy, rather than conduct energy away from the bond site, reduces the initial laser energy required for fusion. Likewise, the more efficient focusing of the laser energy when the laser is operated in the tem_{00} mode reduces the fusion bonding requirement. With less laser energy required, there is less heat available for axial transfer away from the bond site, and thus crystallization is reduced.

The mere selection of laser bonding, from among several known approaches to fusion bonding, provides no assurance against the unwanted crystallization and stiffness. The doctrine of

"inherency" cannot be grounded upon possibilities or probabilities. Rather, the result advanced as "inherent" must be an inevitable result of the circumstances from which the result is said to arise. Ethyl Molded Products Co. v. Betts Package, Inc., 9 USPQ 2nd 1001 (D Kentucky 1988), citing In Re Ulrich, 212 USPQ 323 (CCPA 1981). Jang, in suggesting laser bonding as but one of several alternatives, and failing to suggest either the careful selection of the laser wavelength in view of the involved polymers or an appropriate laser operational mode falls far short of this standard. Accordingly, Jang fails to disclose a balloon catheter in which a fluid tight fusion bond between the catheter tubing and neck regions of a dilatation balloon are within .030 inches of the tapered regions, yet leave the tapered regions substantially free of crystallization.

Accordingly, it is submitted that the balloon catheter of Claim 16 is not anticipated by Jang.

Claims 17, 18 and 22-25 depend on Claim 16 and are patentable for reasons given in connection with Claim 16.

Further as to Claim 17, the Jang patent fails to teach the claimed neck portions with inner diameters substantially equal to the outer diameter of the catheter tubing in the region of the fusion bond. To the extent that Jang's monolithic catheter with several lumens can be likened to the claimed catheter and neck portions, there is no teaching of the claimed relationship as to respective diameters. Rather, the bonds in Jang simply close off the lumens.

Further as to Claim 18, Jang fails to teach the claimed annular structure of the fusion bonds. Rather, the bonds in Jang are semi-circular.

Further as to Claims 22 and 23, these claims contemplate catheter tubing and dilatation balloons being constructed of

different materials. In the Jang patent, the catheter material and balloon material are inherently the same, since balloons are formed by first forming lumens in the monolithic catheter. This difference is significant in view of the practical requirements of balloon catheters. The catheter shaft must be relatively stiff at the proximal end, with decreasing stiffness as it approaches the balloon end of the catheter. The balloon must have a precise amount of distensibility, depending upon the preferences and requirements of physicians. The monolithic structure of Jang cannot meet these disparate requirements.

Further as to Claim 24 and 25, Jang fails to teach or suggest the process steps of selecting a monochromatic energy wavelength to at least approximately match the wavelength of maximum spectral absorption of the balloon and catheter materials, nor does Jang teach concentrating the energy as claimed.

Claims 16-18, 22, 24, and 25 stand rejected under 35 U.S.C. §102(b) as anticipated, either by U.S. Patent 4,950,239 (Gahara et al.) or U.S. Patent 4,276,874 (Wolvek et al.).

Gahara discloses angioplasty balloons and catheters, including a version (Figures 4-6) in which proximal and distal flanges (necks) of the balloon are bonded to the catheter. The overlap for bonding is 2 millimeters. Gahara suggests heat welding, solvent welding, ultrasonic welding, hot-melt bonding, and adhesive bonding (column 4, lines 45-51). The patent does not mention laser bonding, nor does it discuss any bonding approach in depth. The patent does not mention crystallization.

The Wolvek patent discloses an elongatable balloon catheter used in inter-aortic pumping. Wolvek does not disclose laser bonding, but mentions bonding by adhesives, heat sealing, welding and "windings" (column 6,lines 6-9). The catheter includes a

stainless steel tip 32 and a stainless steel rod 46, moveable axially by manipulating luer fittings 26a and 26b. The balloon is "deflated" by moving the stainless steel rod distally to stretch the balloon thin. The balloon is "inflated" by proximally moving the stainless steel rod.

As to Gahara, the office action appears to rely principally upon Figure 5 and column 4, lines 47-51, as teaching the claimed catheter. This passage, however, mentions nothing about an axial distance between a tapered region of the balloon and the associated bond. The 2 millimeter overlap teaches that the bond must be at least within 2 millimeters (.080 inches) of the tapered region, and of course allows for a bond that is directly adjacent to the tapered region, by virtue of being 2 millimeters in axial dimension. However, there is no suggestion or teaching that the tapered region is free of crystallization.

Again, the doctrine of inherency is relied upon to supply what is missing from the Gahara disclosure.

As for the Wolvek patent, the relied upon passage (lines 7, 8 and 13-18 of column 6) teaches even less than Gahara, simply listing several alternatives for bonding, none of which involve a laser, and disclosing no dimensions whatsoever. There is no mention of balloon tapered portions substantially free of crystallization, and the Patent and Trademark Office is forced to rely upon an alleged "inherency" of this feature.

This reliance fails, for all the reasons given above in connection with the Jang patent. Further, the Gahara and Wolvek patents cannot anticipate the present invention, in their utter failure to mention laser bonding. Again, it is pointed out that crystallization is the inevitable result of conventional fusion or heat welding.

Claims 19-21 stand rejected under 35 U.S.C. §103 as being

unpatentable over the Jang patent.

Claim 19 requires the axial dimension of the distal fusion bond to be at most .030 inches. Claim 20 further restricts the dimension to about .020 inches. Finally, Claim 21 provides that the distal fusion bond is less than .010 inches from the distal tapered region.

In connection with this rejection, it is asserted in the office action that the motivation to reduce cost would lead one skilled in the art to minimize use of material. This is said to lead toward reducing the size of the neck region. This contemplates reducing the axial distance between the bond and the tapered portion, reducing the axial dimension of the bond itself, or both.

Cost reduction, while certainly of concern, is a minor consideration as compared to catheter and balloon efficacy, in maneuvering through tortuous arteries and withstanding high dilatation balloon burst pressures. It is clear from the present specification that balloon and catheter maneuverability is a primary motivation for positioning bonds as near as possible to the tapered portions, especially the distal tapered portion. Also clear is the motivation to maintain balloon capability to withstand high burst pressures, despite a narrowing of bonds. See, for example, the objects of the invention at page 3 of the specification.

A recognition of objects and motivations, whether toward lower cost or more effective performance, is no substitute for a teaching in the prior art as to how these motivations and objects might be realized. Only the applicant has disclosed a manner of fusion bonding which results in the claimed balloon catheter structure. While Claims 19-21 focus upon the bond dimension and bond spacing from the tapered region of the dilatation balloon,

these claims also include the features of Claim 16, in particular the freedom of the balloon tapered regions from crystallization.

In the present action it is stated that "Jang teaches using laser bonding, which as admitted by applicant is capable of a bond within the claimed dimensions". Indeed, laser bonding, as taught by the applicant, is capable of forming balloon catheters as defined in Claims 19-21.

By contrast, Jang merely mentions "laser bonding" as one of several alternatives. Some of the alternatives are known to be inappropriate, e.g. vulcanization bonding, solvent bonding, and ultrasonic bonding. Thus, Jang does not teach fusion bonding approach capable of yielding bonds of the claimed dimensions and with the nearly adjacent tapered regions being free of crystallization, as required in Claims 19-21.

New Claims 26-31 are drawn to a balloon catheter in which a dilatation balloon and a catheter are bonded along a distal neck of the balloon. The distal tapered region of the balloon is free of crystallization, despite the close proximity of the bond. Therefore, Claims 26-31 are patentable, for reasons given in connection with Claim 16.

In summary, Claims 16-31 incorporate subject matter patentable over the prior art of record, and define this subject matter with the clarity and precision required by 35 U.S.C. §112, second paragraph. An early and favorable action allowing these claims is respectfully requested.

Respectfully submitted,

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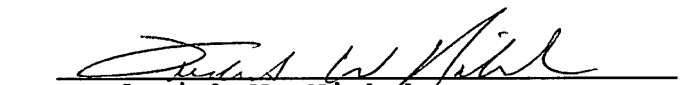

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